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BIOMET MICROFIXATION

SEP 19 2012

510(k) Summary

April 24, 2012

Contact: Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218-2480

Sheryl Malmberg, RA Specialist
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Device Name: Biomet Microfixation Sternal Closure System **Common Name:** Plates and Screws

Classification Name: Single/multiple component metallic bone fixation appliances and accessories

Device Product Code: 87HRS (21 CFR 888.3030) **Device Classification:** Class II

Intended Use: Biomet Microfixation Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including Sternal fixation following Sternotomy and Sternal reconstructive surgical procedures, to promote fusion. The Biomet Microfixation Sternal Closure System is intended for use in patients with normal and poor bone quality.

Description: The Biomet Microfixation Sternal Closure System (sometimes abbreviated SL) of plates, including the SternaLock Blu system, is made up of plates of varying shapes currently including, but not limited to, X plates, box plates, straight plates, and L plates. The plates have at least one cuttable cross section, but not more than 4 of these sections when they are intended to cross a non-transverse fracture or sternotomy. There are plates without cuttable cross sections to assist in the fixation of transverse fractures. The plates accept screws with a diameter of 2.4mm and 2.7mm. Self-drilling screws have a maximum length of 20mm. The tip of the self-drilling screw is designed so that a predrilled hole is not required, but may be used. See chart below for more detail.

Material: Titanium

Sterility Information: The Biomet Microfixation Sternal Closure System will be marketed as non-sterile, single use devices. Validated steam sterilization recommendations are included in the package insert.

Possible risks:

1. Poor bone formation, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
2. Nonunion or delayed union, which may lead to breakage of the implant.
3. Migration, bending, fracture or loosening of the implant.
4. Metal sensitivity, or allergic reaction to a foreign body.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
7. Increased fibrous tissue response around the fracture site and/or the implant.
8. Necrosis of bone.
9. Inadequate healing.
10. Selection of screws which are longer than the depth of the sternum may cause possible impingement on structures internal to the chest wall including vessels, pleura and other structures.

Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant.

Substantial Equivalence: Biomet Microfixation considers the Biomet Microfixation Sternal Closure System to be equivalent to the Biomet Microfixation Sternal Closure System (K011076, K110574 and K111908). There are no changes to the screws.

The SternaLock (sometimes abbreviated SL) system of plates, including the SternaLock Blu system, is made up of plates of varying shapes currently including, but not limited to, X plates, box plates, straight plates, and L plates. The following design features are common to this family:

1. Material:
A. All SL plates are machined from Grade IV commercially pure titanium as governed by ASTM F-67.
2. Thickness:
A. **Min/Max** –The minimum nominal thickness for plates offered is 0.063 inches thick (as in the SL Blu system) while the maximum thickness plate is 0.102 inches thick (as in the earlier SL system).
3. Holes for Screw Fixation:
A. **Screw Diameter** – the plates are compatible with SL screws with a diameter of 2.4mm to 2.7mm. B. **Minimum Distance** – between screw holes is 0.260 inches. C. Plates have at least 1 but not more than 4 holes on either side of each cuttable cross-section.
4. Cuttable cross-section: Many of the SL plates are designed with at least one tie spanning the sternotomy line to facilitate emergent re-entry by cutting through the tie(s).
A. **Cross-sectional area** – this is $0.006in^2$ through the tie for all SL Blu system plates, and $0.005in^2$ for all earlier SL system plates. B. **Span** – The shortest span of these cuttable cross-sections is 0.056 inches (part number 73-1952). The longest span of these cuttable cross-sections is 0.382 inches (part number 73-2634). C. **Quantity** – The plates have at least 1, but not more than 4 of these ties, when they are intended to cross a sagittal fracture or sternotomy.
5. Transverse Fracture Plates: These plates do not need cuttable cross-sections because they are intended for fixation of transverse fractures which do not cross the sternotomy line.
A. The plates intended for fixation of transverse fractures are distinguished by the absence of cuttable ties. The plates may have from 2 to 26 holes.

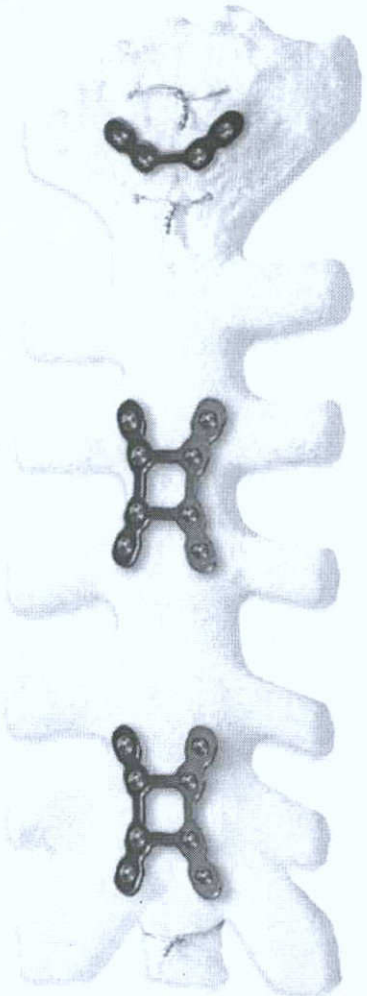

Figure 1. Recommended sternal closure plating with SternaLock Blu.

The design of new plates for the SL systems must satisfy all of the above conditions, however it is not limited in configuration.

Conclusion: Mechanical testing such as tensile strength, shear strength and screw pull out have been conducted and used to demonstrate substantial equivalence in that the devices will perform within the intended use and that no new safety and efficacy issues were raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 19 2012

Biomet Microfixation
% Ms. Sheryl Malmberg
Global Regulatory Affairs Specialist
1520 Tradeport Drive
Jacksonville, Florida 32218-2480

Re: K121302
Trade/Device Name: Biomet Microfixation Sternal Closure System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: August 23, 2012
Received: August 24, 2012

Dear Ms. Malmberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Mark N. Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K121302

Device Name: Biomet Microfixation Sternal Closure System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE iF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Anton Dmitriev

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121302